OPHTHALMIC TECHNOLOGIES INC.

OCT/SLO
Dual Channel
Imaging System

Service Manual

Model-B

- *Version: V 4*
- *September 2005*
- *Ophthalmic Technologies Inc.*

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OCT/SLO System
Introduction and Theory of Operation

The OCT/SLO is an Optical imaging system designed to image the vitreo-retinal structure, the retinal layers as well as provide a confocal fundus image. It is based on a dual channel system, built around an interferometer and a confocal receiver. The OCT channel resolves retinal structures by measuring the time delay of light that is back-scattered from different micro-structural layers in the retina. It produces cross-sectional images (B-Scan) or coronal (C-Scan) images of the retina. The confocal receiver operates similar to a scanning laser ophthalmoscope (SLO) and produces fundus images of the retina and the optic nerve.

The OCT/SLO operates in two scanning modes:

- B-Scan OCT - producing cross sectional images

and

- C-Scan OCT – producing coronal images

In both modes of operation, two images are simultaneously produced and displayed, one OCT and the other Confocal image of the fundus. The OCT/SLO uses light generated from an infrared broadband **S**uper **L**uminescent **D**iode (SLD) source with a wavelength between 790 nm to 950 nm. The interferometer combines the reflected light from the retina with the reflected light from a reference mirror. A photo-detector unit detects and measure the interference and sends the signal to a computer that generates the OCT image. Part of the light backscattered from the retina is also diverted to a photo-receiver via a small pinhole, the photo detector detected the signal which is then amplified and sent to the same computer which generates a Confocal Ophthalmoscope image of the fundus simultaneously with the OCT image. As both the confocal fundus (retinal surface) image and the OCT images are generated through the same optics at the same time, they are displayed simultaneously on the computer screen and are pixel to pixel correspondent.

In the **B-Scan Mode** the OCT/SLO projects light onto to the retina through Galvano-Scanning mirror system which moves the beam in a horizontal line (vertical line or diagonal or circular line). The OCT image is analogous to ultrasound B-Scan and represents a longitudinal cross sectional image of the retina, its sub-layers and internal structures.

In the **C-Scan (Coronal) Mode** the OCT/SLO projects the light into the retina through a pair of X,Y Galvano-Scanners which move the beam in a raster fashion across the surface of the retina. . The C-Scan Coronal OCT images are plane generated at different (preset and pre-selected) Z depths. Each C-Scan OCT represents a X,Y Plane at a given Z depth.

Another choice allows the user to produce successive intra-sections of the OCT and the Confocal Ophthalmic image. In the C-scan regime, the OCT/SLO system can also be switched into a fast regime of operation which allows collection of a sequential stack of images at different depths to provide a Topographic Map. The topographic map has the same resolution irrespective of the pixel within the transverse area of the raster image, due to the *en-face* scanning used in the OCT/SLO.

The user may select:

(i) the scanning depth range from 0.5 to 6.0 mm in user pre-selected steps;
(ii) the scanning field/angle (width of the scan, or lateral size in the B-scan regime and width and height of the raster image in the C-scan regime) from 15° to 25°;
(iii) the scanning rate, either 1Hz or 2Hz (frames per second) in the B-scan regime or 2, 4, 8, 16, 32 Hz (frames per second) in the C-scan regime

In the C-Scan, when selecting the scanning depth range, the number of C-Scan slices is altered, with a maximum of 240 slices or cuts per stack.

Characteristics
Description

The OCT/SLO system is an imaging system intended to be used for ophthalmic applications. It combines a digital fundus imaging system that includes a Confocal Scanning Ophthalmoscope **CSO** and Optical Coherence Tomography **OCT**. Both the Confocal fundus SLO image and the OCT image are produced simultaneously from the same SLD light source through the same optics and therefore they are pixel to pixel correspondent.

The OCT/SLO software runs on Windows XP, and uses the features of the Windows interface to direct the operation of the system and maintain patient records, permitting a user-friendly environment for clinical applications.

System components

The OCT/SLO system consists of:

The Scanner unit or Optical Head, which contains the optical emitter/receiver. An attached computer for system control, image capture, patient data storage, Image recall and display and image analysis.

Application

To acquire SLO and OCT images, the operator first selects the "SLO/OCT" tab which displays the acquisition screen, and follows the instructions for its various controls (displayed on the upper left corner of the screen). The patient placed their head on the chinrest and is instructed to fixate on the internal or external fixation target. The scan parameters are preset, the examiner selects the scan mode of his/her choice, select "LIVE" and the system starts scanning the eye.

Specifications

TOMOGRAPHIC IMAGING

Purpose: Cross sectional imaging of fundus
Signal Type: Optical scattering from tissue
Signal Source: Super Luminescent Diode (SLD) 820 nm
Optical Power: <1000 Microwatts at cornea. SLD current will shut off if safety circuit is activated (upon scanner-motion failure)
Spot Size at Retina: 20 μm.
Longitudinal/Axial Resolution: <10μm. in tissue
Transverse Resolution: 20μm. in tissue
Scanners: Galvanometric with X,Y mirrors
OCT Scan Patterns: Longitudinal XZ (B-Scan), Fast (stack) Topography with 3D OCT, Coronal En-Face XY (C-Scan), Freedom Examination: user footswitch (or mouse) controlled combination of B-Scan and C-Scan, Optional in Advance User mode: Detailed Stack (C-Scan) and Radial Scan and RNFL program.
Scan Pixels: Adjustable – 1024x1024, 512x512, 256x256 and128x128 Scan
Speed: Variable – 1, 2, 4, 8, 16, 32 frames/second.
Scan Acquisition Time: Longitudinal – 1, 2 frames/second.
Coronal (C-Scan) – 2, 4, 8, 16, 32 frames/second
Longitudinal and Coronal (Depth) Scan Range: Variable 0.1 – 6.0mm.

FUNDUS IMAGING

Purpose: Confocal Fundus image for alignment, orientation and registration of the OCT image and the topographic maps and for diagnostic purposes
Signal Type: CCD image and Confocal Ophthalmoscope.
Field of View: up to 25°
Viewing Method: 19” LCD Color Display Monitor
Internal Fixation: 0.8” LCD display, User/computer controlled with variable pattern and Size.
External Fixation: Slit lamp type adjustable LED

ELECTRICAL

Imaging System only:
Single phase:
100V ~ systems: (±10%), 3.5A
115V ~ systems: (±10%), 2.6A
230V ~ systems: (±10%), 1.3A
Total Power requirements and Power consumption for:
Imaging system, PC computer, LCD monitor and Motorized Table:
100V ~ : (±10%), 12.0A 1KVA
115V ~ : (±10%), 10.6A 1KVA
230V ~ : (±10%), 5.3A 1KVA
Main fuses: for 100V ~ & 115V 2 each 8.0A. for 230V ~ 5.3A

CONTROL UNIT (Specifications current at time of writing)
CPU: 2.6GHz Pentium 4, 1GB DDR RAM
Monitor: 19" Color LCD Monitor
Control Input Devices: Keyboard, Mouse, Joystick
Storage: 160GB Hard Disk

ENVIRONMENTAL CONDITIONS
Transport and Storage
Temperature: –10 to +60 deg. C
Relative Humidity: 30% to 70%, excluding condensation
Atmospheric Pressure: 500 hPa to 1060 hPa
Operation
Temperature: +17 to +27 deg. C
Relative Humidity: 30% to 70%, excluding condensation
Atmospheric Pressure: 700 hPa to 1060 hPa

DIMENSIONS:
Scanner:
59x67x55cm
41kg
Power Supply:
22x48x20cm
16kg

Note: System specification may change from time to time by the manufactuere to to improvamnet in components performance or other technical reasons.

Set-up and Maintenance

The system will be installed and put into operation by only OTI staff or its official representatives.

Warranty Note: The OCT/SLO system requires that all replacement parts be replaced by OTI certified parts. Any attempt to repair and/or replace any of the system parts by the user without written approval by OTI will void the system warranty. All repairs and replacement of parts should be preformed by OTI service staff or OTI official representatives.

OTI Software upgrades and Software updates: OTI will provide users with User-installed software updates. These updates should be installed whenever the user receives them from OTI. Users are required to confirm with OTI in writing that the have updated the software to the current version.

Error Messages: When the OCT/SLO system displays an Error Message, please provide the service department with the error message and the serial number of your system for quicker and better service assistance.

System Cleaning: The only parts of the system that require cleaning are the forehead and the chin rest (these are the parts that come with patient's contact regularly). These parts should be cleaned between each examination with an alcohol prep swab. The user can also use a 2% glutaraldehyde solution for disinfection, however these two solutions may cause skin irritations, so it is important to make sure to wipe these parts with a clean soft wet cloth after the application of these disinfection solutions.

System Front Lens Cleaning: It is important to make sure that the system front lens does not contact the patient eye or face. If the lens contacts the eyelashes or any other part of the patient's face, it is important to clean the dust and oily smudges occasionally. Any oily smudges or major dust on the ocular lens will reduce the quality of the OCT and SLO images. To clean the lens you may user a Kodak (or other) "lens cleaning paper" with a "lens Cleaning solution". Always use lens cleaning paper to avoid scratching the front lens. To clean the lens dip or spray the lens cleaning paper in the cleaning solution and wipe the lens in circular motions from the centre of the lens outwards. Make sure that the lens is dry and without any residue (left after the cleaning), before you proceed with the next exam.

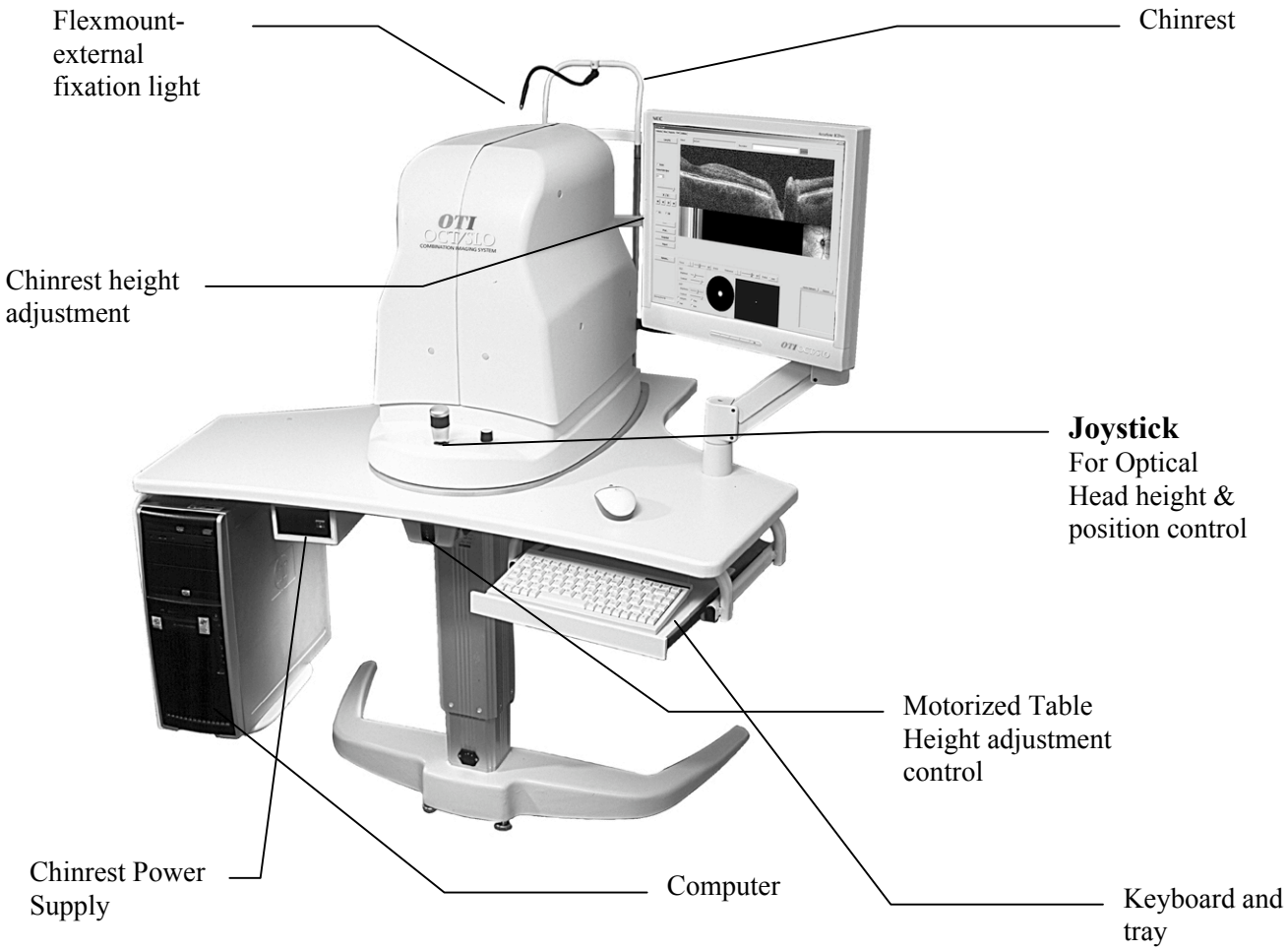
Set-up and Maintenance

Power Fuse Replacement: There are number of power fuses installed in different parts of the system key components. Only OTI service personal or its official representatives are authorized to replace any of the system's power fuses. Any attempt to replace any of the system power fuses by non authorized personal will void the system warranty and may cause major damage to some of the system key components.

Moving the OCT/SLO system: If the unit has to be moved to a new location, the user should contact OTI or its official representative to arrange the packing and re-installation of the system.
OTI or its representatives will not be responsible over any of the system functions or performance unless the system was Packed, unpacked installed and tested by OTI staff or its official representative.

Clinical Setup:

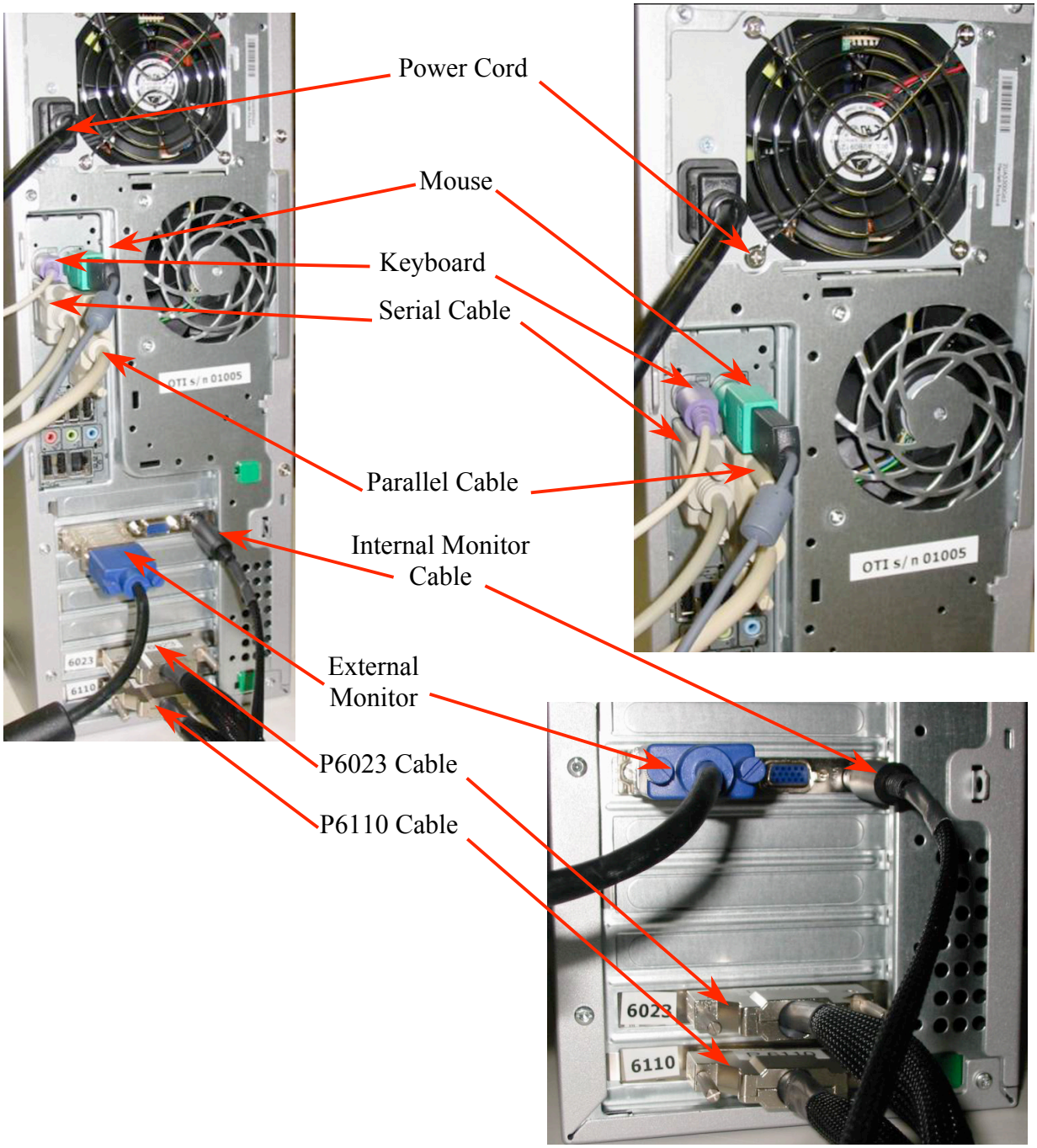
System Description – Full View



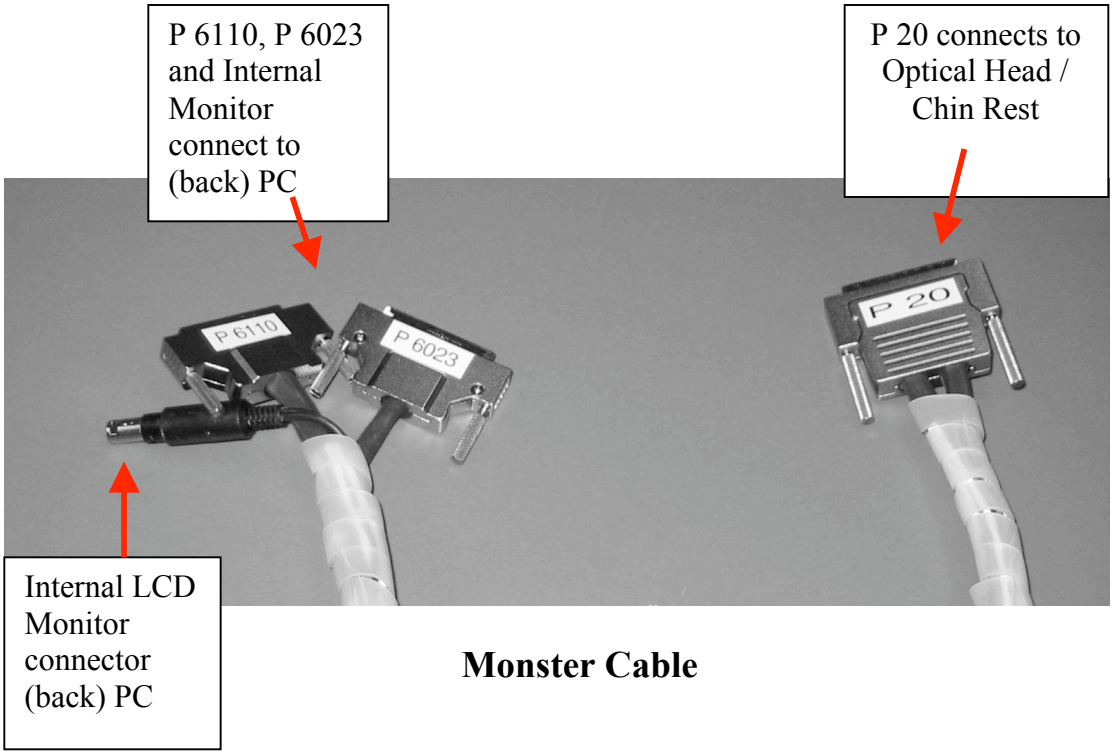
The Keyboard Tray and the Computer shelf can be installed on either side of the motorized table.

Only OTI Service representative or OTI trained Service personal should assemble and install the OCT/SLO System. Any installation by other than OTI personal or OTI trained personal will void the system Warranty. The system should be setup in a room with air conditioning or at least a stable ambient temperature. The system will be delivered in several parts; the optical head and chinrest (pre-assembled), the PC, the up/down table and the power supplies. As well as this there is a box containing external cables and other components such as the keyboard and mouse.

System Description – Computer Wiring Connections



Cables:



Monster Cable

Connections from the Chin Rest to the rear of the PC are:

- Monster cable: Two 68 pin Cables connected to boards Marked P 6110 and P6023.
- Serial Cable
- Parallel Cable
- Internal Monitor Cable

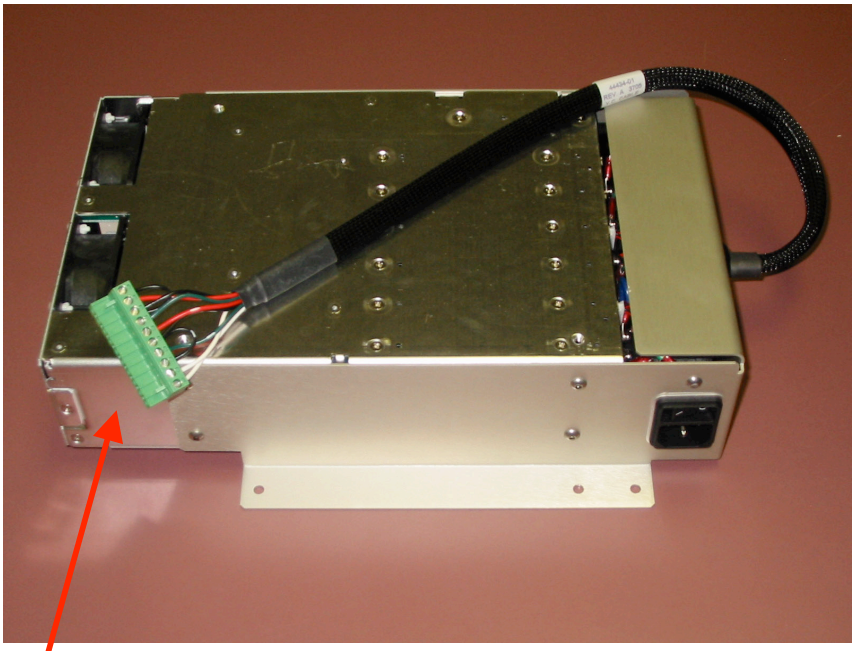
Other Connections to the PC are:

- External LCD Monitor VGA Cable
- Mouse
- Keyboard
- External Power Cord

Other Connections from or to the Chin Rest are:

- OCT/SLO Power Supply connector
- Monster Cable Connector P20 connects to the Optical Head/Chin rest
- Chin Rest Power connecting to Chin Rest power supply (allows chin rest Up & Down motion through the Joystick
- External Fixation wire connects to the Chin Rest Power Supply

Optical Head Power Supply



Optical Head Power Supply Connector

Note: Please make sure not to connect the Power connector in a Backward/reverse way. Such reverse connection will cause major damage to internal components of the optical head

Connections bottom of the Optical Head /Chin Rest

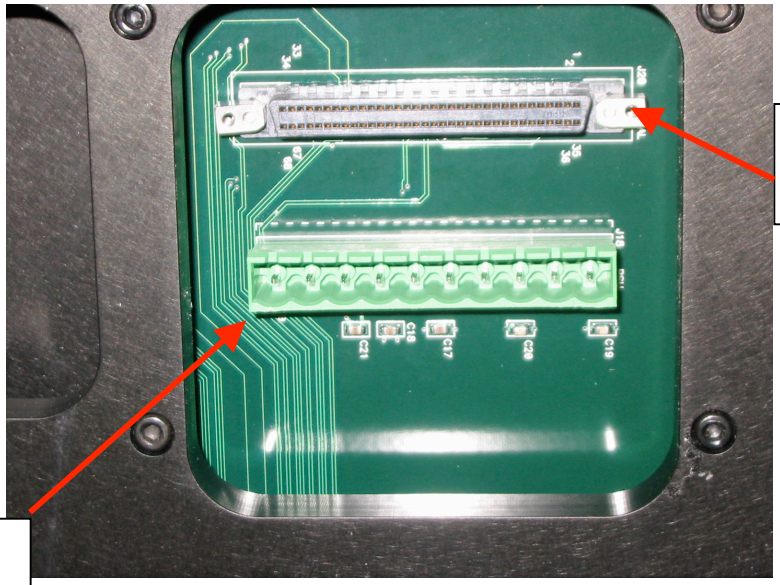
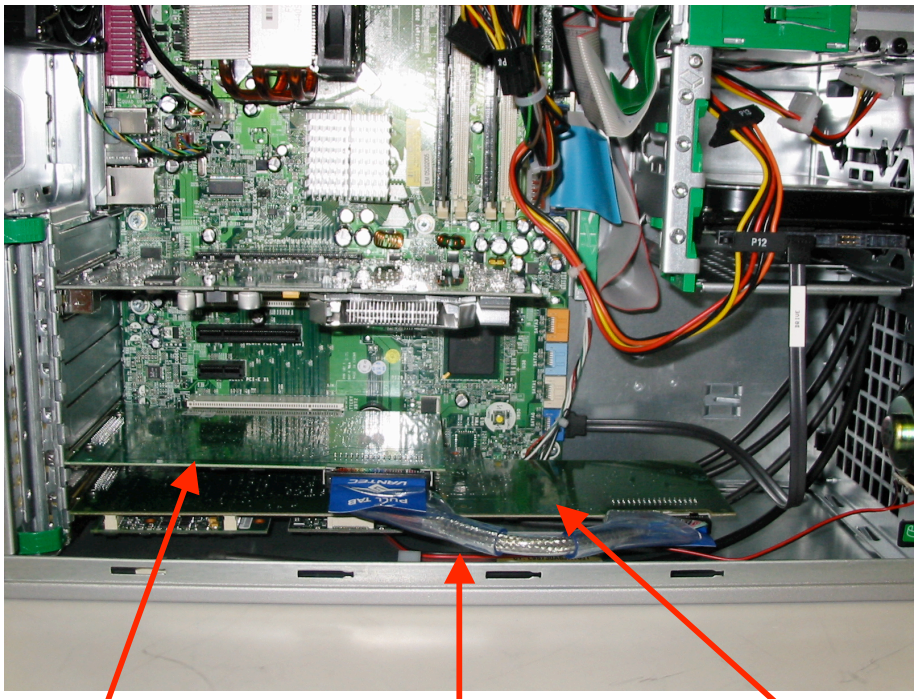


Image Capture and I/O Boards (PC)



Initialization Process:

After assembly is completed, the system should be powered up and ran to check initialization.

Please follow the steps below :

1. Power "ON" machine, check all cables are attached and boot up the computer (Initialization program should run automatically after login). If Initialization fails again, please contact the manufacturer.
2. Initialization should take less than 10 minutes. If there are any problems during initialization it may be helpful to enter the service mode. Otherwise go to the SLOOCT tab and click ***live*** to begin acquisition. (see User Manual)

Service mode:

1. Go to the utilities tab.
2. Click on "**Service"** and enter the password '***room13***'
3. Go to Diagnostics and you should see the ongoing communication between the PC and the system during initialization.
4. If the system fails to initialize check the power supply and cabling to the optical head.
5. Otherwise contact the manufacturer product service personnel.

Important Information:

C-Scan Settings
Transverse and Longitudinal Panes: Sets image size and calibration parameters.
Stage INIT: Lists COM port number (if connected direct to PC should be port 1, if via USB to serial converter should be port 3).
AutoAlignment:JIG: Trigger Voltage shows the lower limit for re-adjustment and upper voltage the upper limit for re-adjustment.
Reconstruction: used for image sizing and adjustment.

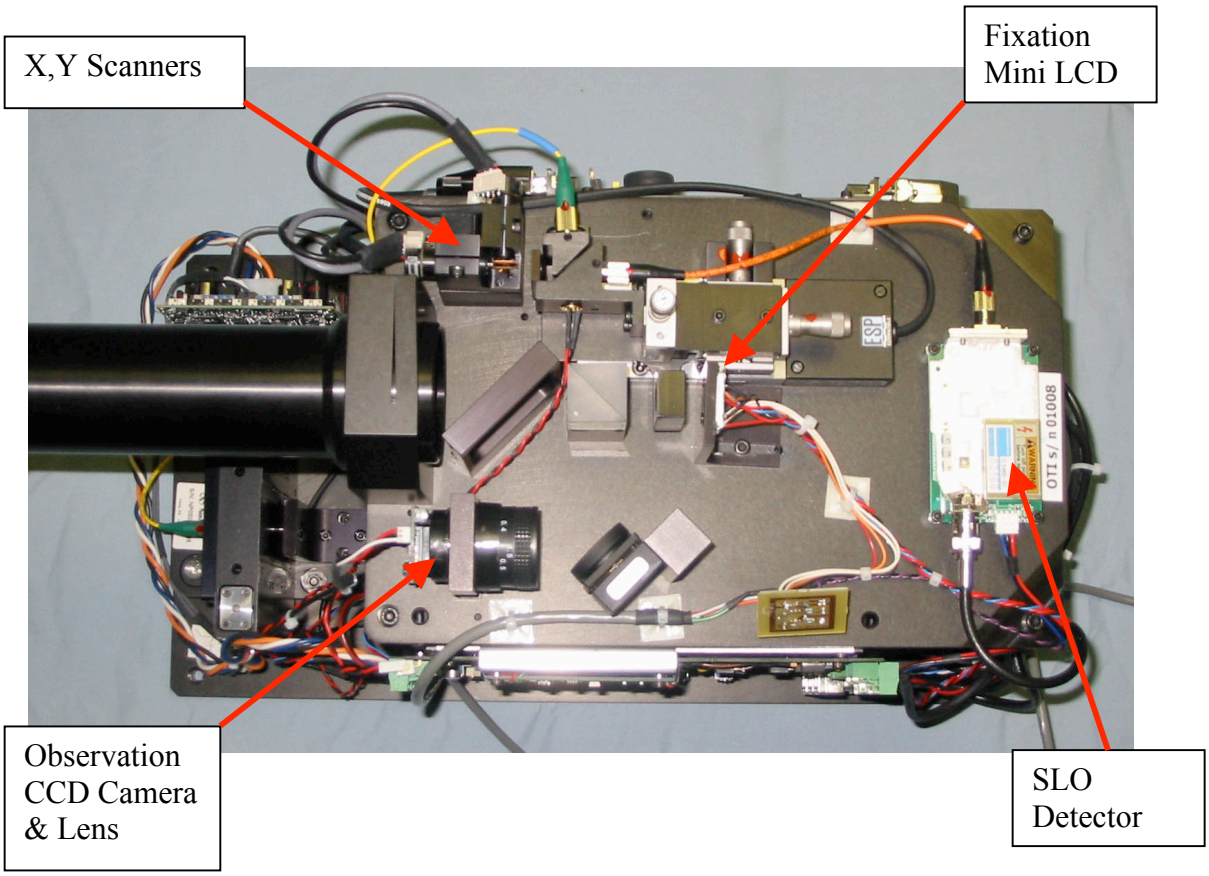
Parts Replacement:

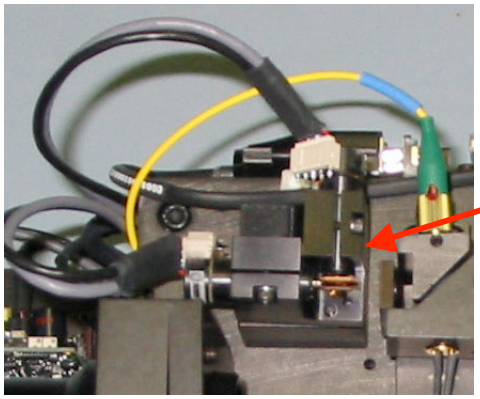
Replacement of any of these parts must be performed by the manufacturer trained personnel. OTI will not be responsible for any work or replacement of parts performed by any person other than OTI personnel.

The Replaceable parts in the system are:

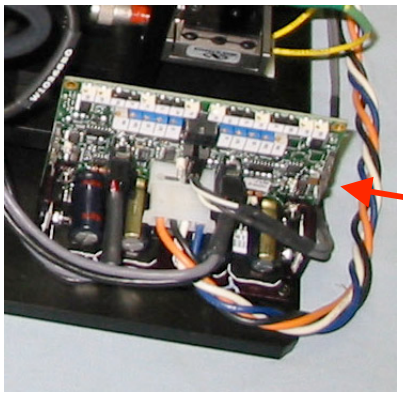
- X,Y Galvoscanner Model 6210
- X,Y Scanners Controller Board
- Axis 3 & 4 MFN- type Fiber Alignment stages.
- Observation CCD Camera assembly
- Fixation Mini-LCD & assembly
- MCB Stages Controller
- SLD Pilot4 Controller
- OCT Electronics Detector Box
- SLO Detector
- NI Image Capture Board
- NI I/O Board

Optical Head Top View

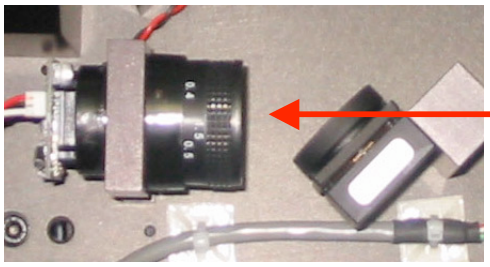




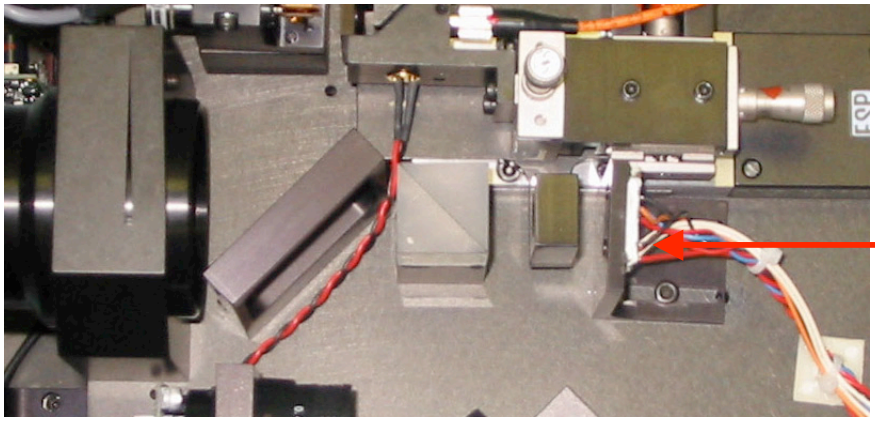
X,Y Scanners



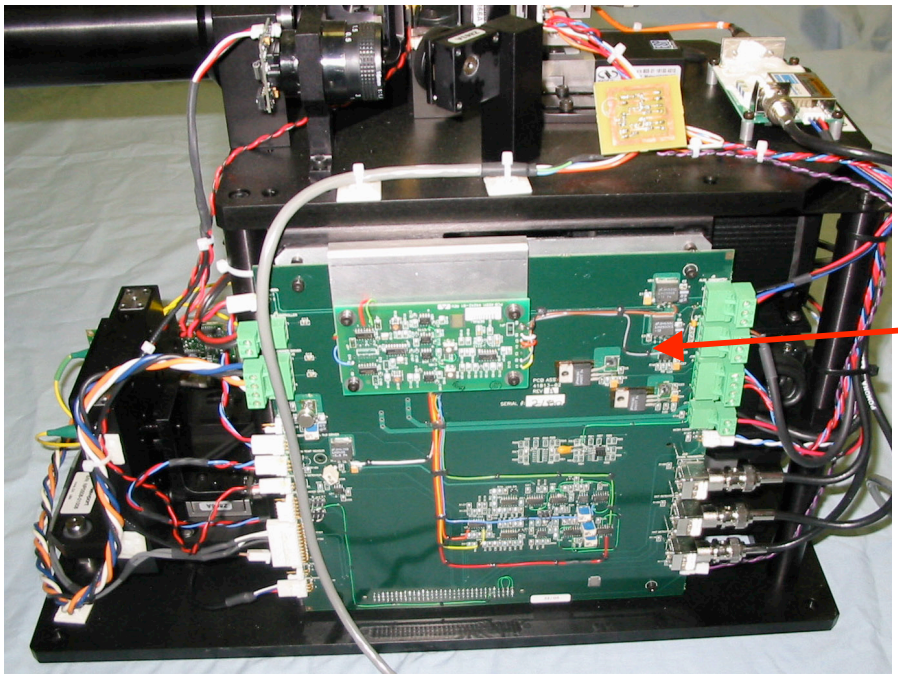
X,Y Scanners
Controller Board



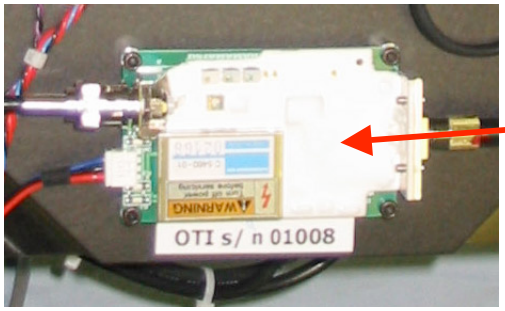
Observation CCD
Camera & assembly



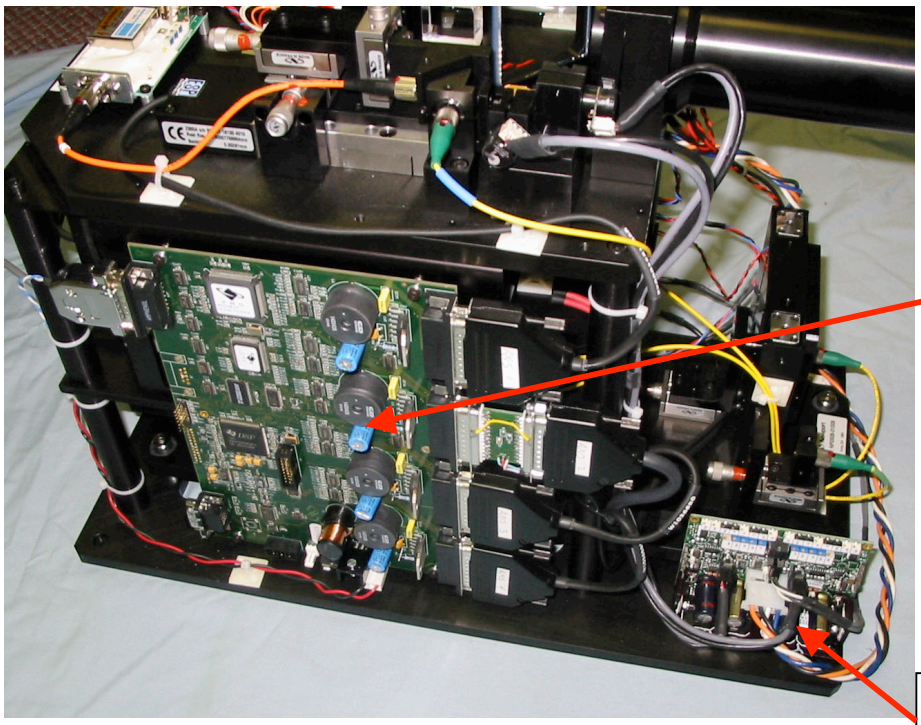
Fixation Mini LCD Assembly

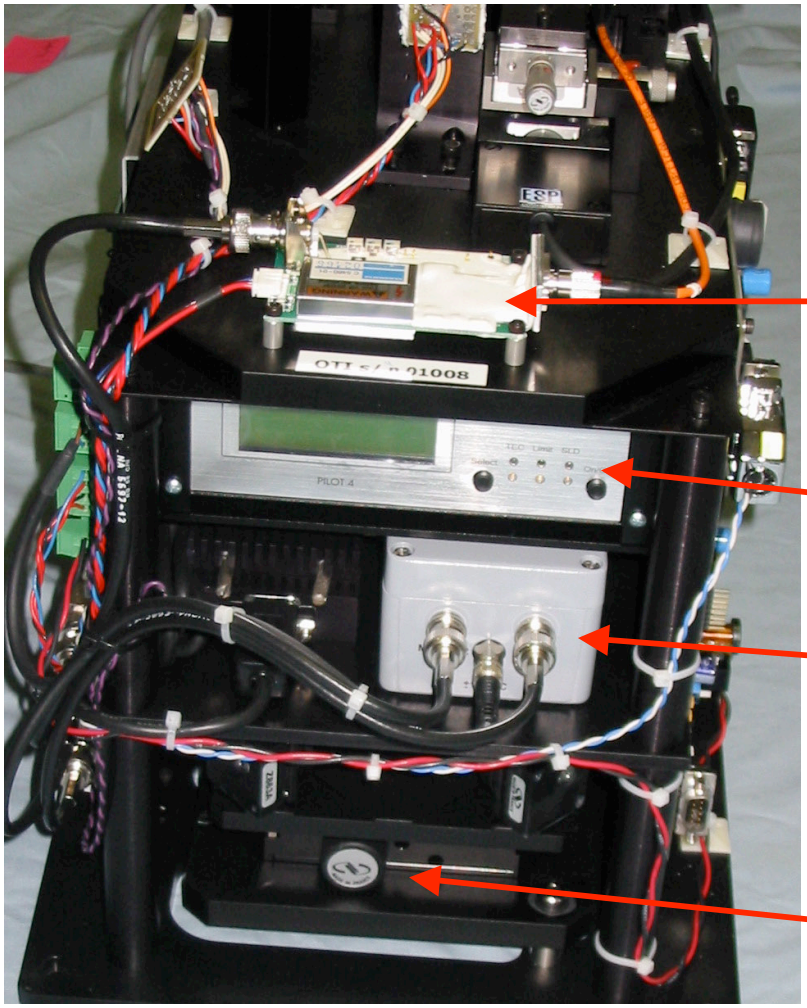


Optical Head Interface Board & Safety Board



SLO Detector


MCB
Stages
Controller
Board
X,Y Scanners
Controller Board


SLO Detector
SLD Pilot 4 Controller
OCT
Detector &
Electronics
Main Ref. Stage

Procedures Warning

Generally all the following procedures are performed with all 3 parts of the upper covers removed.. **Great care must be undertaken when removing or replacing the covers as many problems can be started simply by adjustment of the covers**. Specific problems to look for when replacing the covers are:

- Pressing on the 'blue' fiber may cause degradation of final image quality, or complete machine failure.
- Pinching of the electrical cables may cause hindrance of movement of the optical head or in-ability to close the covers.

***** It is the responsibility of the Technical Service Personal to make sure that the quality of the work and the handling of the system components is done in accordance to the manufacture requirements and recommendations. OTI will not be responsible for any work or replacement of parts which is performed not to standards or by any person other than OTI personal.***

Replacing Scanners

Tools required: M3 and M4 hex screws and allen keys, spare XY scanner set, PC and software. Service password.

Part 1, Replacement

1. REM: scanners are matched to individual driver boards and matched to axes, do not mix up.
2. Ensure power is off to scanners (total supply or just 10pin power cable).
3. Unplug cables from driver boards and scanner head.
4. Unscrew driver boards and replace.
5. Unscrew scanner mount.
6. Remove mount and swap scanner head.
7. When replacing scanner mount push toward closest corner of scanner module plate while tightening screws.
8. Reconnect cables.
9. Proceed to Alignment after reconnecting power and restarting software.

Part 2, Alignment

1. Ensure that the scanner mount is fixed correctly.
2. Check that the cables are connected correctly at the driver board and scanner head.
3. Ensure system is powered up and the software is running correctly.
4. Go to service menu.
5. Click on c-scan settings tab, switch between this tab and the SLOOCT (capture) screen.
6. Click start and change to 4fps.
7. Adjust the focus so that it is at either zero dioptres correction or 3500, depending on software version.
8. Now adjust X and Y offset using the buttons to centre the lens reflection in the SLO image. Horizontal position can be checked by rotating the red line. The output offsets should be the opposite sign but the same amplitude of the input offsets.
9. When finished go to C-Scan settings.
10. Click UPDATE.
11. Go to SLOOCT (normal acquisition) tab.
12. Check SLO reflection
13. The software offsets should not be more than 2.5V. If the offset is there is an alignment problem with the camtech scanner and mechanical alignment should be used.

Warning: Power to the eye should be re-checked after scanner replacement. Go to section 'Safety and Power to the Eye' in this manual.

Protocol for Replacement of MFN stage Axis 3/4

Tools required: Crosshead screwdriver, Metric Allen key set M2-M6, spare MFN stage, cutters and cable ties.

In all cases, beware of damage to fibres and grease marks on glass surfaces, lenses and any other optical parts.

1. The upper cover should be removed, all 3 parts.
2. The system should be booted up and run to see if there is any obstruction to movement, while looking at the diagnostic panel and the machine.
3. If there is no obstruction and the axis does not work, proceed.
4. Switch of PSU box but leave computer on with diagnostic screen visible.
5. Disconnect 4-pin power cable from chinrest.
6. Carefully cut all cable ties that hold axis cable. You may have to undo the M6 bolt holding the MFN cable in place.
7. Pull back the cable 'press' for the yellow fibre.
8. Undo the 4 bolts holding the bracket for axis 3 in place.
9. Hold so that the yellow fiber is not pulled.
10. Remove the 4 bolts so that the axis 4 MFN is removable.
11. Slide out the axis 4 MFN.
12. Feed through the cable for the new MFN and position, being careful not to apply too much pressure on the 3x URM3.5 mounting assembly for fiber injection.
13. Reattach all bolts and cables.
14. Switch power on to the system.
15. Using the diagnostic screen, check that the axis 4 MFN can perform a home search. Visually check that the movement of the 2x MFN assembly is un-impeded.
16. The 'true' position for axis 4 alignment may now have changed. But first try an alignment with the original axis 3 and 4 positions. Restart software to perform a search cycle. If this is not found, next try and add 180 microns to the axis 4 position. Again, try and perform a search cycle by restarting software. If this does not work, remove 180 microns from the original position. If this does not work, try 360 and then removing 360 from the axis 4 position. If successful go to 18.
17. To be complete, 16 may need to be repeated by adding 180 to the axis 3 position repeating 16, and if unsuccessful removing 180 from the axis 3 position and repeating 16. This is to take into account tolerances in the MFN height.
18. Record new alignment positions.

Protocol for Replacement Mini-LCD

Tools required: Large Crosshead screwdriver, spare Mini-LCD assembly, monitor and alignment JIG.

1. Attach the mini-LCD alignment JIG to the lens barrel of the machine. The LCD-alignment jig should be attached to a monitor.
2. If the current mini-LCD is to be replaced, remove it now and reconnect cables to the new LCD.
3. Ensure the 3 holding screws are loose so that the assembly may be adjusted, but firm enough that the assembly does not move before fixing.
4. Run the system and set the scan rate at 32 fps zoomed.
5. Adjust the focus of the system so that the scan pattern is clearly displayed on the monitor in a sharp fashion. To do this you may need to adjust the power of the SLD drive current as set on the pilot 2 or 4 to zero. If this is the case, do not start or stop the scanning as this will cause the system to begin jigging to find the 'correct' alignment position.
6. Once focused, adjust the position of the mini LCD assembly to focus the cross on the monitor. At this point, lateral position is unimportant. Once focused, fix and switch to B/C scan usually by pressing F6.
7. Now adjust the position of the fixation cross with the mouse and when centered, use the ctrl-alt-shift and right click to set the default fixation position.
8. Fix screws with varnish.

The system should be booted up and run to see if there is any obstruction to movement, while looking at mini-LCD.

Protocol for Alignment of Observation CCD Camera

Tools required: Crosshead screwdriver, camera alignment JIG.

The upper cover should be removed, all 3 parts.

1. Attach Camera alignment JIG to lens barrel.
2. Move external chinrest illuminator to 'backlight' the opaque target on the JIG assembly.
3. Check camera image is beingdisplayed correctly on the PC monitor (check all connections).
4. Adjust the tip/tilt assembler and the focus of the camera lens. Ensuring the iris of the camera lens is fully open, adjust to centre a sharp crosshair in the camera image.

Replacement of PILOT 4

Time to complete: 5 to 10 minutes
Tools: Crosshead screwdriver, flat-head screwdriver, spare PILOT, Optical power meter.

Precautions: Never remove power to PILOT4 while SLD is on if possible, ABSOLUTELY never remove 9-pin D-type connector while SLD or PILOT is on.

1. Write down 'Current Limit', 'Drive Current', 'Thermistor' and 'PD monitor' settings from PILOT to be replaced when on (if possible). If these values are not available, necessary values may be obtained from OTI.
2. Switch off power to PILOT.
3. Remove D-type connector and unplug safety cables (these go to scanner feedback positions).
4. Unscrew power cable from terminal 14 and 16.
5. Replace new PILOT, attach power cables but do not attach D-type connector or safety cable.
6. Switch on power and check PILOT functions (LEDs should light red for TEC and SLD).
7. Adjust Current Limit and Drive current values using a small flat head screwdriver. Check Thermistor value is at 10 (kiloOhms).
8. Switch off PILOT.
9. Attach D-type cable and screw in, couple safety circuit cables from Camtech scanners.
10. Switch on system and check that when scanners 'run', SLD switches on, and when scanners stop, SLD switches off.
11. Go to section 'Safety and Power to the Eye' to finish.

Safety and Power to the Eye

***Take extreme caution when conducting the following procedures**:*

Required: IR viewer, Calibrated Optical Power Meter.

After performing the following actions, power to the eye should be re-checked:

- Replacement of scanners
- Replacement of PILOT controller

Preferably two people are required, one to use the IR viewer hold the power meter head, and one to call out measurements.
For this measurement, a range of focusing positions may be tried at a zoomed scanner setting and running longitudinally.
If the measured value differs by that expected from either the previous current limit setting or 700 microwatts by more than 10% inform OTI immediately.

Troubleshooting:

Q; The system only shows every other longitudinal (B-scan) image.
A: Check the cable connection from the encoder to the PC. Especially the internal PS2 cable and also the internal 15-pin D-type connector to the MCB.

Q: The system performs correctly, but will not switch to B-scans.
A: Check for a broken connection on the 15-pin D-type connection cable attached to the MCB.

Q: Vertical Bands Appearing in OCT image.
A: Electronic root, caused by either, variation of symmetry of DC power supply to the low noise +/-15V supply, or miss-adjustment of the SYM (symmetry) potentiometer on the current OCT electronics box. This may happen when the voltage is switched from 120V to 100V on the isolation transformer. An earlier optical cause reported should now be solved.
Another possible solution is to replace the X-scanner cable between the scanner driver and scanner head. If neither of these solutions work, please inform OTI.

Q: Internal LCD noisy.
A: Bad solder contact, swap with correctly functioning unit.

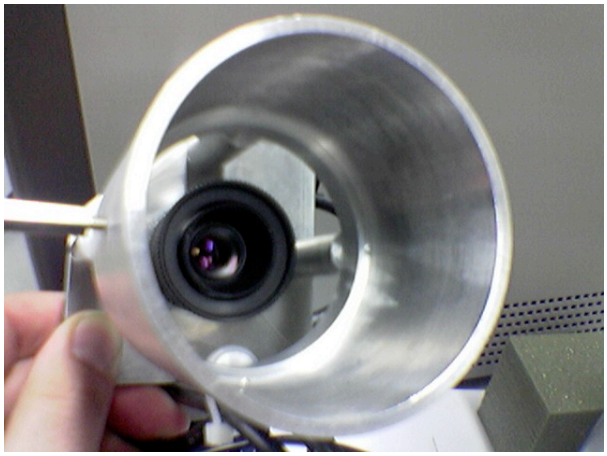
Q: Main screen showing negative temperature.
A: After checking the cables are correctly connected between the PC and the chinrest and that power is on. This could be breaking of the cable for temperature sensor, replace with new one, correctly cable tied. This is the internal PS2 connector between the chinrest base and optical head.

Q: ‘Criss-cross’ Noise in the SLO channel.
A: Primary cause is power supply noise. Check that power supply conforms to noise requirements and if it does not replace.

Warning:

- Any replacement of parts which are listed in this service manual without written confirmation from OTI will void any warranty provided by the manufacturer – OTI.
- Replacement of any parts which are not listed in this service manual or the entire optical head is against OTI recommendation and it will void any warranty provided by the manufacturer – OTI.
- OTI will be only responsible to performance and safety of the system if the replacement parts are provided and inspected by OTI. Replacement of any parts of the system with parts not provided by OTI will void any warranty as offered by manufacturer - OTI.

JIGS for Setup and Alignment

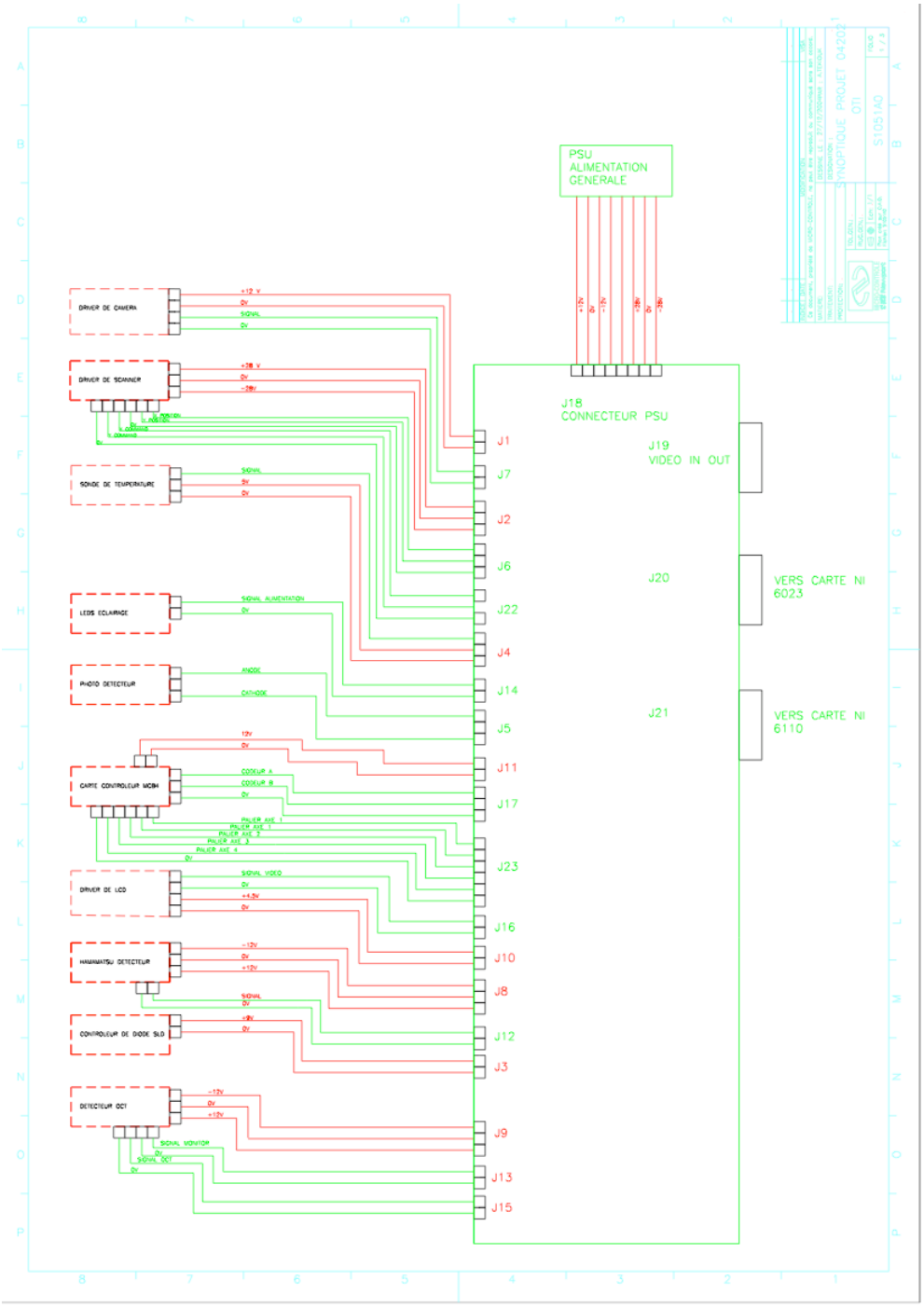


Jig for LCD Alignment

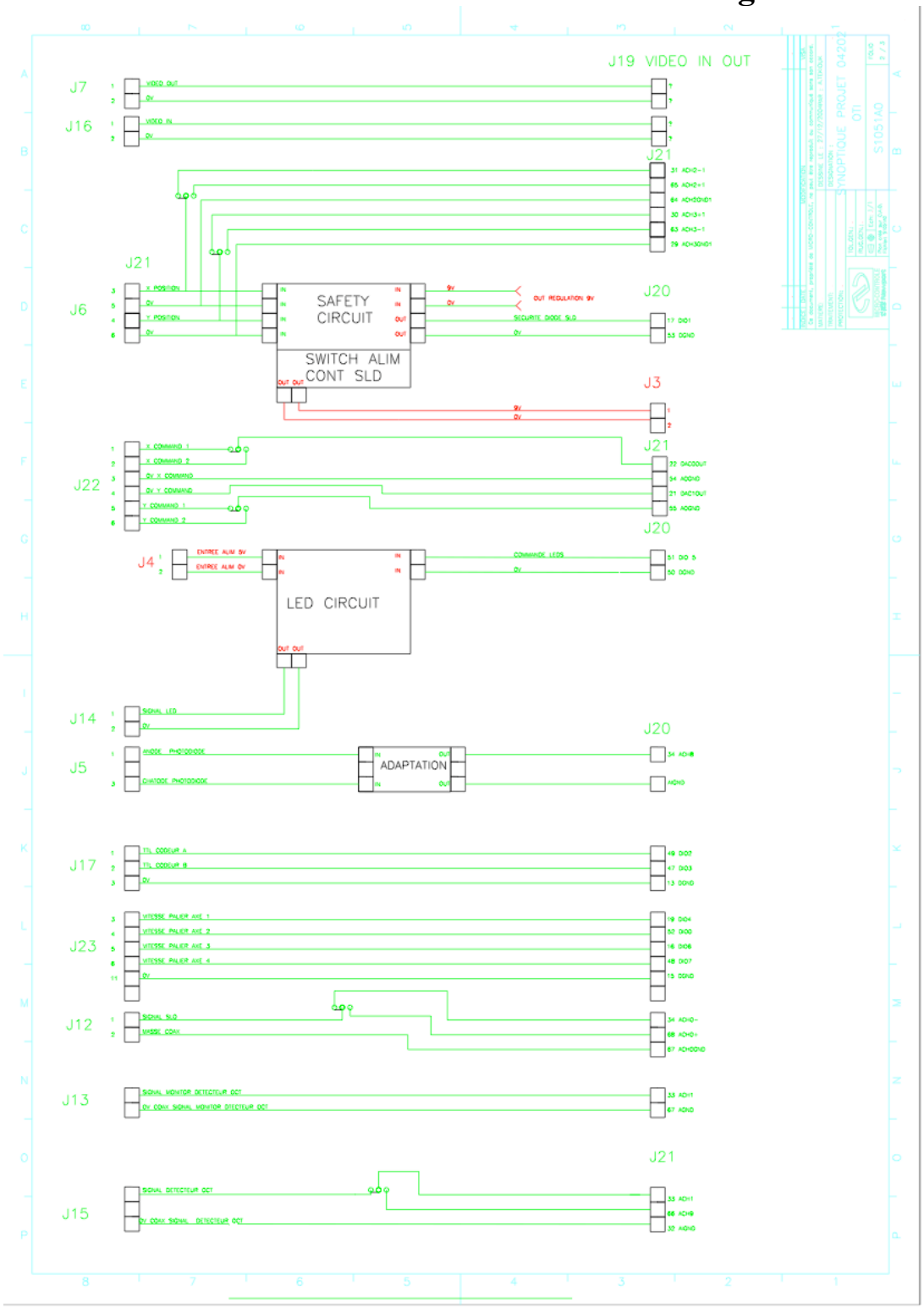
Jig for Image Calibration

Jig for Camera Alignment

OCT/SLO Wiring Diagrams
S1051A0 Electrical Schematic



S1051A0 Interface Board Drawing



S1051A0 Optical Head Power Supply Drawing